

AMENDMENT (2003)

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Claims 10-21 have been canceled, claims 1, 3, 4, 5, 7 and 8 have been amended and claims 22-24 have been added to more clearly define the present invention.

The Examiner has rejected claims 1-4, 7, 8, 13-16 and 18-21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

In response thereto, the Applicants have amended claims 1, 3, 4, 5, 7 and 8 to overcome the Examiner's objection with regard to terminology, such as, for example, the term "stable", as well as other inconsistencies in the claims. The Applicants appreciate the Examiner's thorough reading of the specification and claims and submits that the present amendment overcomes the Examiner's rejection of claims 1-4, 7, and 8, 10-21 being canceled by this amendment.

Claims 1-3, 9-11, 16, 17 and 21 have been rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,996,193 in view of Hackh's Chemical Dictionary. Claims 11, 16, 17 and 21 have been canceled and the Applicants herewith traverse the Examiner's rejection of original claims 1-3 and 9 on the basis of the amended claims. The amended claims now define the present invention

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in terms of an emulsion having a stabilizing amount of Pemulen in water suitable for topical application to ocular tissue.

Clearly, there is no reference in the Hewitt reference which suggests or teaches the use of Pemulen and, further, the compositions taught in Hewitt are not suitable for ocular tissue. Accordingly, the Applicants respectfully request the Examiner to withdraw the rejection of the subject claims under 35 U.S.C. 102(b).

Support for the present amendment to the claims regarding topical application to ocular tissue occurs throughout the specification and specific reference to Pemulen is shown in the examples.

Claims 4-8 and 12-15 have been rejected by the Examiner under 35 U.S.C. 103 as being obvious over the Hewitt et al reference in view of Hackh's Chemical Dictionary, in view of U.S. Patent No. 4,839,342 to Kaswan. In this rejection, the Examiner states that Hewitt et al does not teach the use of castor oil in the composition, and therefore, the Examiner looks to Kaswan as disclosing castor oil as a known pharmaceutically acceptable excipient for use in cyclosporins and is functionally equivalent to olive oil, mineral oil, petroleum jelly, and alcohol excipients. The Examiner, therefore, concludes that it would have been obvious to one of ordinary skill in the art

at the time of the Applicants' invention to use the pharmaceutical carrier of Hewitt et al and to substitute for the olive oil component of Hewitt the castor oil excipient disclosed by Kaswan.

Claims 12-15 have been canceled and claims 4-8 depend from amended claim 1, which defines the present invention in terms of an emulsion including Pemulen suitable for topical application of ocular tissue. While the Kaswan reference is directed to a method for treating an aqueous-deficient dry eye state in a patient, there is no suggestion in the reference of the use of Pemulen as a stabilizing agent. Since all of the references are silent with regard to a Pemulen teaching, the Applicants respectfully request the Examiner to withdraw his rejection of claims 4-8 as amended under 35 U.S.C. 103.

Claims 16, 18 and 20, rejected by the Examiner under 35 U.S.C. 102(b) have been canceled.

Original claims 1-3, 9-11 and 16-21 have been rejected by the Examiner under 35 U.S.C. 103 as being obvious over U.S. Patent No. 5,364,632 to Benita et al. In this rejection, the Examiner states that Benita et al discloses emulsions comprised of hydrophobic drugs such as indomethacin, steroids such as testosterone and testosterone propionate and

cyclosporin; a vegetable oil such as soybean oil, cotton seed oil, olive oil, and sesame oil, which inherently contain higher fatty acid glyceride and a surfactant such as polysorbate 80. As noted hereinabove, claims 11-21 have been canceled; however, with regard to the rejection of claims 1-3 and 9, as presently amended, it is clear that there is no teaching of Pemulen in this reference and accordingly, this silence cannot be the basis for a rejection of these claims under 35 U.S.C. 103.

The Applicants have amended the present claims to define the pharmaceutical composition/emulsion as being suitable for topical application to ocular tissue. This limitation is critical in view of the toxicity of excipients such as olive oil and the like. The formulations are relied on by the Examiner fall in the class discussed by the Applicants in the original specification, namely, oily preparations which contain higher fatty acid glycerides such as olive oil, peanut oil and/or castor oil, which produce an unpleasant sensation when applied to the eye because of these oils.

The Applicants have discovered a formulation which is an emulsion which is essentially non-irritating to the eye. This characteristic distinguishes the present invention from the references cited by the Examiner.

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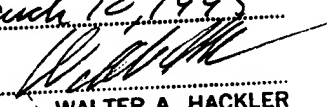
In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectfully requested.

Respectfully submitted,



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